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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0632; FRL-9924-86]

Thiram; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of thiram in or on banana.

Taminco US, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0632, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to

4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0632 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0632, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8268) by Taminco US, Inc., Two Windsor Plaza, Suite 411, Allentown, PA 18195. The petition requested that 40 CFR 180.132 be amended by establishing a tolerance for residues of the fungicide thiram, in or on banana at 0.8 parts per million (ppm). That document referenced a summary of the petition prepared by Taminco US, Inc, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for thiram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiram follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Thiram is a dimethyl dithiocarbamate fungicide. Thiram has been shown to cause neurotoxicity following acute and subchronic exposures. In the acute and subchronic neurotoxicity studies submitted, neurotoxicity is characterized as lethargy, reduced and/or tail pinch response, changes in the functional-observation battery (FOB) parameters, increased hyperactivity, changes in motor activity, and increased occurrences of rearing events. No treatment-related changes were observed in brain weights or in the histopathology of the nervous system. In a non-guideline study published in the open literature, chronic feeding of thiram to rats caused neurotoxicity, with onset of ataxia in some animals 5-19 months after

beginning of treatment. However, no evidence of neurotoxicity was seen following chronic exposures in mice or rats in guideline studies submitted to the Agency. The chronic toxicity profile for thiram indicates that the liver, blood, and urinary system are the target organs for this chemical in mice, rats, and dogs. There is no evidence for increased susceptibility following *in utero* exposures to rats or rabbits and following prenatal and postnatal exposures to rats for 2 generations. There is evidence of quantitative susceptibility in the developmental neurotoxicity (DNT) study. However, there is low concern for the increased susceptibility seen in the DNT study since the dose response is well defined with a clear no-observed-adverse-effect-level (NOAEL) and this endpoint is used for assessing the acute dietary risk for the most sensitive population. Thiram is classified as “not likely to be carcinogenic to humans” based on lack of evidence for carcinogenicity in mice or rats. There are no mutagenic/genotoxic concerns with thiram. The available toxicological database for thiram suggests that this chemical has a low to moderate acute-toxicity profile.

Specific information on the studies received and the nature of the adverse effects caused by thiram as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Thiram. Update to the Aggregate Risk Assessment to Support the Requested PHI Reduction and Increased Tolerance Request on Strawberry,” p. 9 in docket ID number EPA-HQ-OPP-2012-0925.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the

toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for thiram used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of February 12, 2014 (79 FR 8295) (FRL-9904-22).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiram, EPA considered exposure under the petitioned-for tolerances as well as all existing thiram tolerances in 40 CFR 180.132. EPA assessed dietary exposures from thiram in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

A partially refined probabilistic acute dietary-exposure assessment was performed using 100 percent crop treated (PCT), tolerance-level residues the highest residue found during field-trials, distributions of field trial residues, and empirical processing factors.

ii. *Chronic exposure.* Tolerances-level residues for banana and average field trial residues for apples, peaches, and strawberries along with 100 PCT were used for the chronic dietary exposure analysis for all crops. Empirical processing factors were also used.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that thiram does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use PCT information in the dietary assessment for thiram. The acute dietary assessment used 100 PCT, tolerance-level residues, the highest residue found during field-trials, distributions of field trial residues, and empirical processing factors; the chronic dietary assessment used average field trial residues along with tolerance-level residues. In addition, 100 PCT were assumed for all food commodities. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for thiram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiram. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of thiram for acute exposures are 0.0478 parts per million (ppm) and 0.0025 ppm for chronic exposures (for non-cancer assessments) for surface water. Ground water sources were not included (for acute or chronic exposures), as the EDWCs for ground water are minimal in comparison to those for surface water. Surface water EDWCs were incorporated in DEEM-FCID into the food categories “water, direct, all sources” and “water, indirect, all sources” for the dietary assessments.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Thiram is not available for sale or use by homeowner applicators; therefore, there are no residential handler exposure scenarios. However, there is potential for residential post-application dermal exposure from treated golf course greens and tees. Residential exposures resulting from dermal contact with thiram-treated turf were assessed for children 6 to <11 years old, children 11 to <16 years old, and adults as described in document “Thiram. Update to the Aggregate Risk Assessment to Support the Requested PHI Reduction and Increased Tolerance Request on Strawberry,” p. 15 in docket ID number EPA-HQ-OPP-2012-0925.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike the *N*-methyl carbamate pesticides, EPA has not found thiram (a dithiocarbamate) to share a common mechanism of toxicity with any other substances, and thiram does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiram does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased susceptibility following *in utero* exposure to rats or rabbits or following prenatal and postnatal exposures to rats. There is evidence of quantitative susceptibility in the DNT study. However, there is low concern for the enhanced susceptibility seen in the DNT study because:

- i. Clear NOAELs/LOAELs were established for the offspring effects.
- ii. The dose-response is well defined.
- iii. The behavioral effect of concern were observed only in females on one evaluation time period.
- iv. The dose/endpoint is used for acute dietary risk for the most sensitive population subgroup (females 13-49 years old). Consequently, there are no residual uncertainties for prenatal and postnatal toxicity.

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3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for thiram is complete with acceptable neurotoxicity, developmental, and reproductive toxicity studies.
- ii. As explained in this unit, there are no residual uncertainties for prenatal and postnatal toxicity.
- iii. There are no residual uncertainties identified in the exposure databases.

EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to thiram in drinking water. In addition, the acute dietary exposure analysis used field trial data along with the 100 PCT. The chronic dietary exposure analysis used tolerance level residues or average field residues along with the 100 PCT. In addition, washing studies were incorporated into the dietary analyses since thiram is not a systemic pesticide and will wash off during normal washing procedures. These assessments will not underestimate the exposure and risks posed by thiram. These assessments will not underestimate the exposure and risks posed by thiram.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. The acute dietary risk estimates are not of concern to EPA (<100% aPAD) at the 95th exposure percentile for the general U.S. population and all other population subgroups. The acute dietary exposure was 62% of the aPAD for females 13-49 years old, the population subgroup with the highest percent aPAD. Therefore, the acute aggregate risk associated with the proposed uses of thiram is not of concern to EPA for the general U.S. population or any population subgroups.

2. *Chronic risk.* The chronic aggregate risk assessment takes into account exposure estimates from dietary consumption of thiram (food and drinking water). The chronic dietary risk estimates are not of concern to EPA (<100% cPAD) for the general U.S. population and all other population subgroups. The chronic dietary exposure was 70% of the cPAD for children 1-2 years old, the population subgroup with the highest estimated chronic dietary exposure. Therefore, the chronic aggregate risk associated with the proposed uses of thiram is not of concern to EPA for the general U.S. population or any population subgroups.

3. *Short-term and intermediate-term risk.* In aggregating short- and intermediate-term risk, the Agency routinely combines background chronic dietary exposure (food + water) with short/intermediate-term residential exposure (dermal only). The combined exposure may then be used to calculate an MOE for aggregate risk. Using the golfer scenario for adult males, adult females, and children >6 years old, combined with the applicable subpopulation with the greatest dietary exposure, the total short / intermediate-term food and residential aggregate MOEs are 570, 540, and 280, respectively. As these MOEs are above the target MOE of 100, the short- and intermediate-term aggregate risks are not of concern. For children <6 years old, there is no residential exposure, therefore, a short / intermediate term aggregate risk assessment is not required for this population.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, thiram is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to thiram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (colorimetric analytical method) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for thiram in or on banana.

V. Conclusion

Therefore, EPA is removing the expiration/revocation date for the current tolerance for residues of thiram, in or on banana at 0.80 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus,

the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 19, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.132, the table in paragraph (a) is revised to read as follows:

§ 180.132 Thiram; tolerances for residues.

(a) * * *

Commodity	Parts per million
Apple	7.0
Banana ¹	0.80
Peach	7.0
Strawberry	20

¹ No U.S. registrations as of September 23, 2009

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